

April 4, 2020

United States Environmental Protection Agency,

This request is made on behalf of myself under the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552.

I am currently retired and a private citizen working on a project that aims to support the transition from animal-based testing to the use of alternative non-animal testing methods for assessing the potential developmental neurotoxicity hazards of chemicals. To this end, the goal of my project is to facilitate the development of non-animal alternative models for development neurotoxicity by informing the comparison to in vivo results. I note that this goal is in line with the Administrator Wheeler’s statement on 09/10/2019 to reduce animal testing by 30% in 2025.

To support my project, I have been collecting, from publicly available sources, information on the results of chemicals tested using EPA or OECD guidelines for neurotoxicity. These sources include regulatory reviews of these studies by the EPA (e.g., DERs), OECD, Health Canada and California EPA. To further my work, I would like to be able to compare my existing data to what the Office of Pesticide Programs has received.

Date Range – 1991-Present

To begin this comparison, I am requesting a listing of all Developmental Neurotoxicity Studies that have been submitted to the Office of Pesticide Products. I would like this to include all studies conducted under:

- 1) The current US EPA Test Guidelines: Developmental Neurotoxicity Study 870.6300
- 2) Or previous versions of developmental neurotoxicity studies, e.g.,
 - a. EPA Series 83-6. Developmental Neurotoxicity Study (sometime also incorrectly identified as 82-9)
 - b. EPA Developmental Neurotoxicity Screen OTS 795.2500
 - c. Any of the older TSCA guidelines (e.g., TSCA Developmental Neurotoxicity Test Guideline Final Rule 53FR5947;February28,1988
- 3) Or 870.3800 - Reproduction and Fertility Effects (August 1998) studies that contain a neurotoxicity cohort
- 4) Or international guidelines for developmental neurotoxicity studies
 - a. OECD Guideline 426 or OECD Guideline 426(draft)
 - b. OECD Guideline 443 (Extended One-Generation Reproductive Toxicity Study with the neurotoxicity cohort)
 - c. EU Method B.53 (Developmental Neurotoxicity Study)
 - d. EU Method B.56 (Extended One Generation Study with the neurotoxicity cohort).

Please include not only studies of active ingredients, but also (to the degree possible) any positive control studies that have been submitted in support of the above mentioned studies.

For these studies I would like the following information:

- 1) The MRID number of the study
- 2) The title of the study
- 3) The year of the study.

Please note that I do not require printed versions of any of this information. An electronic file is acceptable and preferred.

As a private citizen working on research paper that is aimed to be in the public interest I ask that all fees be waived. Disclosure of this information is in the public interest because it is likely to contribute significantly to public understanding of the Agencies activities to promote the development and use of alternative non-animal test methods. I have no commercial interest in the requested information. If the request for fee waiver is denied and fees are expected to exceed \$50.00, kindly notify me by telephone to this effect before this disclosure request is processed. If you have any questions pertaining to any aspect of this request, please call me at 1-919-806-9316 or email me at croftonwork@outlook.com.

Thank you for your assistance. I look forward to receiving your reply.

Sincerely,

Kevin M. Crofton
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